DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Apligraf™
Docket No.: 98E-0846

APR 21 1999

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,485,096, filed by Organogenesis, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Apligraf™, the medical device claimed by the patent.

The total length of the regulatory review period for Apligraf™ is 4,013 days. Of this time, 3,051 days occurred during the testing phase and 962 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun: May 29, 1987.

   The applicant claims that the Investigational Device Exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on July 2, 1987. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on May 29, 1987, which represents the IDE effective date.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: October 4, 1995.

   FDA has verified the applicant's claim that the Premarket Approval Application (PMA) for Apligraf (PMA P950032) was initially submitted on October 4, 1995.

3. The date the application was approved: May 22, 1998.

   FDA has verified the applicant's claim that PMA P950032 was approved on May 22, 1998.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Hollie L. Baker, Esq.
Hale and Dorr LLP
60 State Street
Boston, MA 02109

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service
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# Memorandum

Date: APR 21 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for **Apligraf™**

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned medical device under the Docket Number **98E-0846** stating that this particular patent is eligible for regulatory review. The Patent Number is **4,485,096**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.

DATE: APR 2 1 1999

TO: Sabrina Crisp, Regulations Policy and Management Staff, HF-26

From: Brian J. Malkin, Associate Director for Patents and Hearings, HFY-20

RE: Federal Register Notice Information for Apligraf™
Docket No. 98E-0846, FRDTS# OC9949

Attached is a FR Notice for the medical device, Apligraf™. This document has been internally reviewed and cleared by OHA.

Please note that Apligraf™ is a trademark. Therefore, the superscript "TM" notation will be needed.

Please call me if you have any questions. My number is 827-6620 (Rm. 15-22).

Thank you for your assistance.